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CAMERON KERRIGAN  
SQUIRE, SANDERS & DEMPSEY  
ONE MARITIME PLAZA  
SUITE 300  
SAN FRANCISCO, CA 94111-3492

EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT PAPER NUMBER

1762

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/753,630	<b>Applicant(s)</b> HOSSAINY ET AL. <span style="float: right; font-family: cursive; font-size: 1.5em;">eb</span>	
	<b>Examiner</b> Jennifer K Michener	<b>Art Unit</b> 1762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 12/03.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 40-48 and 50-101 is/are pending in the application.

4a) Of the above claim(s) 63-77, 82-84 and 89-99 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 40-48, 50-62, 78-81, 85-88, 100 and 101 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All    b) ☐ Some \*    c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims 63-77, 82-84, and 89-99 drawn to an invention non-elected in a previous Paper. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Specification***

2. The attempt to incorporate subject matter into this application by reference to 5,069,899, 4,654,327, etc. is improper because the actual text is not incorporated. See below.

3. The amendment filed 12/5/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is found in the added paragraphs to the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

MPEP 608.01 (p) and 2163.07 (b) require the "actual text" of the incorporated material be included. The incorporated material should be included in its entirety and in context.

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Applicant has attempted to characterize the teachings of the incorporated references in a manner not done by the actual references because Applicant has singled out alleged teachings of "aromatic" groups not singled out in the originally-filed disclosure or the references, to support claim limitations rejected under new matter.

For example only, in characterizing the 5,069,899 reference, Applicant states that the reference teaches the "following aromatic ammonium ions", even though this language is not used by the reference. Additionally, while the reference specifically requires "benzalkonium chloride" and the like, Applicant characterizes the reference as teaching all "benazalkonium" (sic) ions, and the like. In regard to the characterization of 3,844,989, Examiner is unable to find a reference to the genus "aromatic", a class of "alkyl aryl" ions or a chemical with vinyl pyridine and benzyl, and the like.

#### ***Claim Rejections - 35 USC § 112***

4. The rejection of claims 53-59 under 35 U.S.C. 112, first paragraph, due to the term "aromatic quaternary ammonium" has been withdrawn in light of Applicant's showings of the teachings of the incorporated references. The incorporated teachings are directed to various examples falling within one of only a very select, small number of genres, namely either the aromatic genus or aliphatic genus. The formal addition of the specification paragraphs, discussed above, is not required to show these teachings.

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5. The rejections of claims 53-60, 40-48, and 61 under 35 U.S.C. 112, first paragraph, regarding the terms "polymeric" and "copolymer of ethylene with vinyl alcohol" have been withdrawn based on Applicant's amendments.

*Based on Applicant's amendment, the following new rejection is made:*

6. Claims 100-101 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Examiner applies this rejection for the same reason as these limitations were objected to for addition into the specification.

***Claim Rejections - 35 USC § 102***

7. Claims 60-62, 50-51, and 78-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Onishi et al. (5,670,558).

Examiner maintains the rejections.

Regarding the newly-added limitations to claims 60 and 62, Onishi teaches the use of one solution, as outlined in the previous office action and below.

8. Claims 60-62 and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Goicoechea (6,010,530).

Examiner maintains the rejection.

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Regarding the newly-added limitations to claims 60 and 62, Goicoechea teaches the use of one solution, as outlined in the previous office action and below.

***Claim Rejections - 35 USC § 103***

9. Claims 58-59, 48, 100-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi in view of Rowland et al. (5,356,433).

Examiner maintains the rejections of claims 58-59 and 48.

Regarding newly-added limitations of claim 58, Onishi teaches the use of EVAL.

Regarding newly-added claims 100-101, Examiner notes that Rowland teaches TDMAC and the benzalkonium ions, as outlined in the previous office actions and specifically required by claim 101. Regarding claim 100, Examiner notes that the ion required by this claim is said to be met by TDMAC by the reference from which it was incorporated, i.e., 5,014,717.

10. Claims 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi in view of Rowland as applied to claims 58-59 and 48 above, and further in view of Hostettler (6,030,656).

Examiner maintains the rejection.

Regarding the newly-added limitation to claim 53, Examiner notes that Onishi teaches EVAL, as discussed in the previous office action and below.

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11. Claims 40-44, 52, 81, and 85-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi in view of Hostettler.

Examiner maintains the rejection.

12. Claims 45-47 rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi in view of Hostettler as applied to claims 40-44, 81, and 85-88 above, and further in view of Shah (6,248,127).

Examiner maintains the rejection.

### ***Response to Arguments***

13. Applicant's arguments filed 12/5/03 have been fully considered but they are not persuasive.

Applicant argues that Onishi refers to two different polymers, the one coated along with the heparin not being EVAL, as suggested by Examiner's rejection.

Examiner disagrees.

Examiner notes that EVAL is not required in all of the claims and therefore polymers from either group would be acceptable as "adhesion enhancers". For claims requiring EVAL, Examiner notes that in embodiment (3), Onishi teaches that the surface lubricating layer, which may include a therapeutic agent, comprises a mixture of the first type of polymer with a functional group and a second type of polymer with another functional group capable of reacting with the first (col. 4, lines 53-57; col. 5, line 4). In

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column 8, EVAL and PVA are taught to be acceptable forms of the second polymer.

Therefore, the reference does teach application of EVAL (or other polymers) with the therapeutic agent, as disclosed in the previous office action, together in a mixture.

Applicant argues that Goicoechea fails to teach that the drug and polymer are both part of the same application solution.

Examiner disagrees.

Goicoechea teaches application of a polymer in solution (col. 4, lines 45-55). This reference also teaches that when radiopaque agents are desired in the coating, that these materials are provided in the coating solution with the polymer (col. 5, lines 1-3). The reference then goes on to say that "Drugs, such as heparin,... may also be incorporated into the polymer coating....These drugs leach out slowly over time....Alternatively, the drugs may be bonded to the surface of the polymer....".

Because the reference teaches that drugs may *also* be incorporated into the coating directly following the radiopaque agents section, it would have been immediately envisioned by one of ordinary skill in the art to include such drugs in the same manner as the radiopaque agents, namely in the polymer solution. Furthermore, it is said that these drugs leach out slowly. If, as Applicant surmises, the drugs are applied after the polymer coating is applied and cured, in a separate solution, the drugs would form a coating on the polymer and would not be held within the matrix from which it leaches. Lastly, the reference teaches that, in the *alternative*, the drugs may be bonded to the surface of the polymer. If this second alternative is to bond the drugs to the surface of



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the polymer coating, then clearly the first alternative is that they were applied *within* the polymer coating. Application of these drugs within the polymer solution, as is done when other agents are to be included, is a fair teaching and reading of this reference and is that which would have been immediately envisioned by one of ordinary skill in the art, which meets the standard for a 102 rejection.

### ***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Kolb Michener  
February 19, 2004



**SHRIVE P. BECK  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700**